

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

In re: NEXIUM (ESOMEPRAZOLE)  
ANTITRUST LITIGATION

MDL No. 2409

Civil Action No. 1:12-md-02409-WGY

This Document Relates To:

All Actions

**MEMORANDUM IN SUPPORT OF PLAINTIFFS'  
MOTION TO COMPEL DEFENDANT RANBAXY TO MAKE A LIMITED  
SUPPLEMENTAL PRODUCTION OF DOCUMENTS**

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## I. INTRODUCTION

Plaintiffs seek from defendant Ranbaxy a narrowly tailored supplemental production of documents that updates portions of Ranbaxy's prior production of documents during the discovery period. The documents plaintiffs seek are responsive to properly served document requests propounded to Ranbaxy in the course of discovery. Ranbaxy responded to these requests by producing responsive documents during discovery. Ranbaxy has a duty to now supplement its responses to the extent it has additional responsive documents. Ranbaxy refuses, however, to make the limited supplemental production plaintiffs request.

Specifically, plaintiffs seek three categories of documents corresponding to four of its document requests previously served on defendants:

- (1) documents and communications between Ranbaxy and FDA concerning its esomeprazole ANDA;
- (2) documents and communications concerning Ranbaxy's performance under an FDA consent decree and import ban; and
- (3) documents and communications between Ranbaxy and AstraZeneca concerning Ranbaxy's performance under their API Supply and Tolling agreements.

A trial in this case commences in seven weeks. But Ranbaxy has produced none of the requested documents. Instead, Ranbaxy has largely stonewalled plaintiffs by claiming that it has no duty to supplement its document responses and objecting on the purported grounds that to supplement its production would be premature and unduly burdensome.

Because Ranbaxy *does* have an obligation to supplement its document production in the eight months since it last produced documents in this case and because the production of documents in response to the limited requests plaintiffs have identified will *not* be burdensome, plaintiffs respectfully move this Court pursuant to Federal Rule of Civil Procedure 37(a) for an

order compelling Ranbaxy to produce the requested documents within 10 days of this Court's order.

## **II. BACKGROUND**

Plaintiffs propounded three sets of document requests to defendant Ranbaxy during the discovery period in this case: Plaintiffs' First Request for Production of Documents to All Defendants ("First RFP"), dated November 21, 2012; Plaintiffs' Second Request for Production of Documents to All Defendants ("Second RFP"), dated May 1, 2013; and Plaintiffs' Third Request for Production of Documents to All Defendants ("Third RFP"), dated July 12, 2013 (collectively, "plaintiffs' RFPs").<sup>1</sup> Ranbaxy last produced documents responsive to plaintiffs' RFPs on December 2, 2013.<sup>2</sup>

On May 21, 2014, plaintiffs requested in a letter to Ranbaxy counsel that Ranbaxy supplement its previous responses to a selected set of plaintiffs' discovery requests as required pursuant to Fed. R. Civ. P. 26(e). Plaintiffs did not request that Ranbaxy search for supplemental documents pertaining to every previous request for production. Rather, plaintiffs asked Ranbaxy to produce additional documents created after the date of its last production responsive to specific requests that plaintiffs had propounded during the discovery period: First RFP, nos. 6-9, 11, 20-22, 24, 54-57, 65-68, 70, and 77; Second RFP, nos. 1-11, 13-14, and 17; and Third RFP, nos. 3-4, 7, 13-15 and 30.<sup>3</sup>

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<sup>1</sup> See plaintiffs' document requests to Ranbaxy attached to the Declaration of Thomas M. Sobol ("Sobol Decl."), at Exhibits A, B and C, respectively.

<sup>2</sup> See e-mail from Marta Markowski to Nexium counsel of record, dated December 2, 2013, concerning the production by Ranbaxy's production of a Site Transfer Amendment filed with FDA, Sobol Decl., Ex. D.

<sup>3</sup> See letter from Christopher Letter to Danielle R. Foley, dated May 21, 2014, Sobol Decl., Ex. E.

On June 10, 2014, Ranbaxy wholesale objected to the entirety of plaintiffs' requests for supplementation largely on the purported grounds that it is under no obligation to supplement its production and that the request for such supplementation is burdensome.<sup>4</sup>

On June 19, 2014, the parties conferred by phone to address Ranbaxy's objections. On June 24, 2014, plaintiffs reduced the number of its requests for supplemental production from 40 to 13 requests: First RFP, nos. 6, 21, 57, 68, 70, and 77; Second RFP, nos. 5, 8-9, and 17; and Third RFP, nos. 7, 14, and 30.

On July 11, Ranbaxy counsel sent a letter to plaintiffs' counsel stating that certain requests were ambiguous and required clarification, and further stating that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]<sup>5</sup>

On July 17, 2014, counsel for plaintiffs and Ranbaxy spoke again and plaintiffs answered all questions for clarification that Ranbaxy counsel posed on their call.<sup>6</sup>

On July 30, 2014, Ranbaxy's counsel sent a letter identifying additional types of requested documents which it purports it does not have and otherwise refused to produce documents responsive to any of the limited, remaining requests, stating that plaintiffs' request for supplementation is "premature . . . at this point":

. . . the extent to which Ranbaxy is obligated to produce any other materials can only be determined after review of Judge Young's

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<sup>4</sup> See letter from Danielle R. Foley to Christopher Letter, dated June 10, 2014, at Sobol Decl., Ex. F.

<sup>5</sup> See letter from Danielle R. Foley to Christopher Letter, dated July 11, 2014 at Sobol Decl., Ex. G.

<sup>6</sup> See correspondence between Christopher Letter and Danielle R. Foley, Sobol Decl., Ex. H.

summary judgment opinions . . . and understanding from there, which, if any, of the requested materials are relevant to the specific issues that remain for trial.<sup>7</sup>

[REDACTED] plaintiffs' supplemental requests now consist of supplementation of *four* of plaintiffs' previous document requests: (1) documents and communications between Ranbaxy and FDA concerning its esomeprazole ANDA (First RFP no. 57); (2) documents and communications concerning Ranbaxy's performance under an FDA consent decree and import ban (Second RFP nos. 8 and 9); and (3) documents and communications between Ranbaxy and AstraZeneca concerning Ranbaxy's performance under their API Supply and Tolling agreements (Second RFP no. 17).

Ranbaxy has not supplemented its production of these requested documents.

### III. ARGUMENT

#### A. Fed. R. Civ. P. 26(e) Requires That Ranbaxy Supplement Its Document Production.

There is no debate that the documents plaintiffs are seeking, and that Ranbaxy has refused to produce, are covered by the document requests that plaintiffs timely propounded during discovery.

It is black letter law that Fed. R. Civ. P. 26(e) places an affirmative duty on a party to fully disclose and then *supplement* disclosure to its adversary.<sup>8</sup> The duty to supplement

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<sup>7</sup> See letter from Danielle R. Foley to Christopher Letter, dated July 30, 2014 at Sobol Decl., Ex. I.

<sup>8</sup> *Klonoski v. Mahlab*, 156 F.3d. 255, 268 (1st Cir. 1998) ("To the extent the rules contemplate additional material that a party finds after it has provided discovery to the other side, the rules require prompt supplementation of its additional material so the opposing party is not misled by the original discovery responses as the opposing party prepares its case for trial." (citing Fed.R.Civ.P. 26(e)). A subsequent First Circuit decision has noted that an amendment to Fed. R. Civ. P. 26(b) has superceded the analysis in *Klonoski* of the scope of permissible discovery under Rule 26(b), see *In re Subpoena to Witzel*, 531 F.3d 113, 118 (1st Cir. 2008), but the discussion of the requirement to supplement pursuant to Rule 26(e) remains good law.

continues after the close of discovery.<sup>9</sup> The continuing duty to supplement is so firmly entrenched that courts warn that “a ‘party may not free itself of the burden to fully comply’ by placing ‘a heretofore unrecognized duty of repeated requests for information on its adversary.’”<sup>10</sup>

Rule 26(e) also recognizes the duty to supplement or correct a disclosure or response with information that is thereafter acquired, as well as information that was not originally provided even though it was available at the time of the prior disclosure.<sup>11</sup> “Information thereafter acquired by a party cannot exclude documents subsequently created by a party, as by creating the document the party most certainly has thereby ‘acquired’ information which it reasonably should know, *i.e.*, ‘learns,’ has rendered its prior response materially inaccurate or incomplete.”<sup>12</sup>

It is precisely these limited types of documents that plaintiffs seek from Ranbaxy—three categories of documents created or received *after* December 2, 2013—and that Ranbaxy unjustifiably refuses to produce. Rule 26 cannot be clearer on this point: Ranbaxy has a duty to supplement its document production and must produce the requested discovery immediately.

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<sup>9</sup> *Id.* at 268. See also *In re BankAtlantic BanCorp, Inc.*, 07-61542-CIV, 2010 WL 3294342 (S.D. Fla. Aug. 20, 2010) (“Courts have held that the duty to supplement continues after the close of discovery.”).

<sup>10</sup> *AVX Corp. v. Cabot Corp.*, 252 F.R.D. 70, 77 (D. Mass. 2008) (quoting *Arthur v. Atkinson Freight Lines Corporation*, 164 F.R.D. 19, 20 (S.D.N.Y.1995) (discussing duty to supplement under Rule 26(e)) and citing 6 James Wm. Moore, *Moore's Federal Practice* § 26.131[3] (2008)). See also *Arthur v. Atkinson Freight Lines Corp.*, 164 F.R.D. 19, 20 (S.D.N.Y. 1995) (finding a duty to supplement discovery where plaintiff's attorney was “certainly aware” that responsive medical records were being generated after an initial response to the authorization for medical records).

Notwithstanding they are not required to do so in order to obtain supplemental responses to their discovery requests, plaintiffs have repeatedly requested that Ranbaxy supplement a limited number of plaintiffs' document requests and made numerous concessions as to the breadth and the number of their requests for which they seek supplementation.

<sup>11</sup> *Klonoski*, 156 F.3d at 268 (“The current version of the rule . . . imposes a broad requirement on parties to update their earlier disclosures and discovery responses.” (citing 8 Charles Alan Wright, Arthur R. Miller & Richard L. Marcus, *Federal Practice and Procedure* § 2049.1 (2d ed. 1994 & Supp.1998))). Accord 6 James Wm. Moore *et al.*, *Moore's Federal Practice* § 26.131 (3d ed. 2010) .

<sup>12</sup> *Robbins & Myers, Inc. v. J.M. Huber Corp.*, 274 F.R.D. 63, 75-76 (W.D.N.Y. 2011) (noting that the 2007 “stylistic” amendment to Rule 26(e) that deleted the phrase “information thereafter acquired” did not narrow the rule and that information “thereafter acquired” is included in the current duty to supplement.)



**B. The Requested Supplementation Does Not Impose An Undue Burden On Ranbaxy.**

Ranbaxy has not, and cannot, demonstrate that the narrowly tailored document requests for which plaintiffs request supplementation impose a burden on it.

First, plaintiffs substantially scaled back their requests for supplementation from forty requests it had propounded during discovery to thirteen requests and, upon Ranbaxy's representations that [REDACTED] [REDACTED] the number of requests for which plaintiffs now request supplementation is four. Not only did plaintiffs scale back the number of requests, but plaintiffs further limited the types of documents it is seeking (e.g., *finalized* documents and communications as opposed to drafts).

Second, any argument by Ranbaxy that searching for the requested documents is burdensome is disingenuous at best. To be clear, assuming Ranbaxy's representations are correct that [REDACTED] [REDACTED] [REDACTED] then the universe of documents that plaintiffs seek is small universe and easily collected. The documents should be readily accessible. Ranbaxy previously produced the same types of documents during discovery and presumably knows where the documents can be located—either in a custodial or in a non-custodial file.

For example, regarding the ANDA correspondence, all pharmaceutical companies are required to keep their ANDA correspondence in an easy to find and access place. This is an FDA requirement. As such, pharmaceutical companies have departments—e.g., Quality Assurance—whose sole function is to comply with FDA recordkeeping requirements and, thus, files regarding all dealings regarding Ranbaxy's esomeprazole ANDA should also be readily available for collection.

#### IV. CONCLUSION

Plaintiffs have been eminently reasonable in their requests for supplementation. Defendants' stonewalling and lack of any supplementation has been far from reasonable and is, simply stated, in violation of the rules governing discovery and Ranbaxy's obligation to supplement its document production to the limited set of requests plaintiffs seek.

For the reasons set forth above, plaintiffs respectfully request that this Court grant the relief requested herein in the form of the proposed order submitted herewith.

Dated: August 19, 2014

Respectfully submitted,

/s/ **Thomas M. Sobol**

Thomas M. Sobol, BBO No. 471770

David S. Nalven, BBO No. 547220

Donna M. Evans, BBO No. 554613

Kristen Johnson, BBO No. 667261

HAGENS BERMAN SOBOL SHAPIRO LLP

55 Cambridge Parkway, Suite 301

Cambridge, MA 02142

Tel: (617) 482-3700

Fax: (617) 482-3003

[tom@hbsslaw.com](mailto:tom@hbsslaw.com)

[davidn@hbsslaw.com](mailto:davidn@hbsslaw.com)

[donnae@hbsslaw.com](mailto:donnae@hbsslaw.com)

[kristenj@hbsslaw.com](mailto:kristenj@hbsslaw.com)

*Liaison Counsel and Co-lead Counsel for the  
Direct Purchaser Class*

David F. Sorensen

Daniel Simons

Caitlin G. Coslett

Nicholas Urban

BERGER & MONTAGUE, P.C.

1622 Locust Street

Philadelphia, PA 19103

Tel: (215) 875-3000

Fax: (215) 875-4604

[dsorensen@bm.net](mailto:dsorensen@bm.net)

[dsimons@bm.net](mailto:dsimons@bm.net)

[ccoslett@bm.net](mailto:ccoslett@bm.net)

Bruce E. Gerstein  
Joseph Oppen  
Elena Chan  
Ephraim R. Gerstein  
GARWIN GERSTEIN & FISHER LLP  
88 Pine Street, 10<sup>th</sup> Floor  
New York, NY 10005  
Tel: (212) 398-0055  
Fax: (212) 764-6620  
[bgerstein@garwingerstein.com](mailto:bgerstein@garwingerstein.com)  
[jopper@garwingerstein.com](mailto:jopper@garwingerstein.com)  
[echan@garwingerstein.com](mailto:echan@garwingerstein.com)  
[egerstein@garwingerstein.com](mailto:egerstein@garwingerstein.com)

*Co-lead Counsel for the Direct Purchaser Class*

Glen DeValerio (BBO #122010)  
BERMAN DeVALERIO  
One Liberty Square  
Boston, MA 02109  
Tel: (617) 542-8300  
Fax: (617) 542-1194  
[gdevalerio@bermandevalerio.com](mailto:gdevalerio@bermandevalerio.com)

Todd A. Seaver (BBO #645874)  
BERMAN DeVALERIO  
One California Street, Suite 900  
San Francisco, CA 94111  
Tel: (415) 433-3200  
Fax: (415) 433-6382  
[tseaver@bermandevalerio.com](mailto:tseaver@bermandevalerio.com)

*Liaison Counsel for the End-Payor Class*

Steve D. Shadowen  
HILLIARD & SHADOWEN LLC  
39 West Main Street  
Mechanicsburg, PA 17055  
Tel: (855) 344-3298  
[steve@hilliardshadowenlaw.com](mailto:steve@hilliardshadowenlaw.com)

Anne Fornecker  
Daniel Gonzales  
HILLIARD & SHADOWEN LLC  
919 Congress Ave., Suite 1325

Austin, TX 78701  
Tel: (512) 851-8990  
[anne@hilliardshadowenlaw.com](mailto:anne@hilliardshadowenlaw.com)  
[daniel@hilliardshadowenlaw.com](mailto:daniel@hilliardshadowenlaw.com)

Kenneth A. Wexler  
Bethany R. Turke  
Justin N. Boley  
WEXLER WALLACE LLP  
55 W. Monroe Street, Suite 3300  
Chicago, IL 60603  
Tel: (312) 346-2222  
Fax: (312) 346-0022  
[kaw@wexlerwallace.com](mailto:kaw@wexlerwallace.com)  
[brt@wexlerwallace.com](mailto:brt@wexlerwallace.com)  
[jnb@wexlerwallace.com](mailto:jnb@wexlerwallace.com)

J. Douglas Richards  
George Farah  
Sharon K. Robertson  
Hiba Hafiz  
COHEN MILSTEIN SELLERS & TOLL,  
PLLC  
88 Pine Street, 14th Floor  
New York, New York 10005  
Tel: (212) 838-7797  
Fax: (212) 838-7745  
[drichards@cohenmilstein.com](mailto:drichards@cohenmilstein.com)  
[srobertson@cohenmilstein.com](mailto:srobertson@cohenmilstein.com)

Jayne A. Goldstein  
POMERANTZ LLP  
1792 Bell Tower Lane  
Suite 203  
Weston, FL 33326  
Tel: 954-315-3454  
Fax: 954-315-3455  
[jagoldstein@pomlaw.com](mailto:jagoldstein@pomlaw.com)

*Co-Lead Counsel for the End-Payor Class*

Richard Alan Arnold  
Scott E. Perwin  
Lauren C. Ravkind  
Anna T. Neill  
KENNY NACHWALTER P.A.

1100 Miami Center  
201 South Biscayne Boulevard  
Miami, FL 33131  
Tel: 305-373-1000  
Fax: 305-372-1861  
[sperwin@kennynachwalter.com](mailto:sperwin@kennynachwalter.com)

*Counsel for Walgreen Plaintiffs*

Barry L. Refsin  
HANGLEY ARONCHICK SEGAL PUDLIN  
& SCHILLER, P.A.  
One Logan Square, 27th Floor  
Philadelphia, PA. 19103  
Tel: 215-568-6200  
[brefsin@hangley.com](mailto:brefsin@hangley.com)

Monica L. Rebuck  
HANGLEY ARONCHICK SEGAL PUDLIN  
& SCHILLER P.A.  
4400 Deer Path Road, Suite 200  
Harrisburg, PA 17110  
Tel.: 717-364-1007  
[mrebuck@hangley.com](mailto:mrebuck@hangley.com)

*Counsel for Rite Aid Plaintiffs*

Bernard D. Marcus  
Moira Cain-Mannix  
Brian C. Hill  
Erin Gibson Allen  
MARCUS & SHAPIRA LLP  
One Oxford Centre, 35th Floor  
Pittsburgh, PA 15219  
Tel.: 412-338-3344  
[bdm@marcus-shapira.com](mailto:bdm@marcus-shapira.com)  
[cain-mannix@marcus-shapira.com](mailto:cain-mannix@marcus-shapira.com)  
[hill@marcus-shapira.com](mailto:hill@marcus-shapira.com)

*Counsel for Giant Eagle, Inc.*

**CERTIFICATE OF SERVICE**

I, Thomas M. Sobol, hereby certify that I caused a copy of this memorandum to be filed electronically via the Court's electronic filing system on August 19, 2014. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system. An unredacted copy of this document will also be sent via e-mail on all counsel of record.

/s/ Thomas M. Sobol

Thomas M. Sobol